(i) The device manufacturer and to FDA within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. Such reports shall be submitted to FDA if the device manufacturer is not known.

(2) Importers are required to submit death and serious injury reports to FDA and the device manufacturer and submit malfunction reports to the manufacturer only:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

(ii) Within 30 days of receiving information that a device marketed by the importer has malfunctioned and that such a device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) Manufacturers are required to submit MDR reports to FDA:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) Within 30 days of becoming aware of information that reasonably suggests a device has malfunctioned and that device or a similar device marketed by the manufacturer would be likely to cause a death or serious injury if the malfunction were to recur; or

(iii) Within 5 days if required by § 803.53.

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers and importers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to a reportable event.

(2) Entities required to report under this part do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to determine that a device-related event is or is not reportable must be contained in the MDR event files, as described in § 803.18.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.21 Reporting codes.

(a) FDA has developed a MEDWATCH Mandatory Reporting Form Coding Manual for use with medical device reports. This manual contains codes for hundreds of adverse events for use with FDA Form 3500A. The coding manual is available from the Division of Small Manufacturer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX 301–443–8818.

(b) FDA may use additional coding of information on the reporting forms or modify the existing codes on an ad hoc or generic basis. In such cases, FDA will ensure that the new coding information is available to all reporters.

§ 803.22 When not to file.

(a) Only one medical device report from the user facility, importer, or manufacturer is required under this part if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event.

(b) A medical device report that would otherwise be required under this section is not required if:

(1) The user facility, importer, or manufacturer determines that the information received is erroneous in that a device-related adverse event did not

occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer. Any reportable event information that is erroneously sent to a manufacturer or importer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured or imported by that firm.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities.* User facilities must provide all information required in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests including dates and laboratory data; and

(7) Description of other relevant history including pre- existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;